DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

LOKTAL MEDICAL ELECTRONICS IND. COM.LTDA- EPP
% Ms. Carrie Hetrick
Emergo Group
816 Congress Avenue, Suite 1400
Austin, Texas 78701

October 8, 2015

Re: K134036
Trade/Device Name: Wavetronic 5000 Digital HF Surgical Unit
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 11, 2015
Received: September 14, 2015

Dear Ms. Hetrick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR [**SELECT ONE:** Part 801 **[or, for IVDs only]** Parts 801 and 809**]**); medical device reporting (reporting of medical device-related adverse events) (21 CFR

803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K134036

Device Name
Wavetronic 5000 Digital HF Surgical Unit and Accessories

Indications for Use *(Describe)*
The Loktal Medical Electronics ind. E com. Ltda EPP - Wavetronic 5000 Digital HF Surgical Unit is intended for resection, ablation, excision of soft tissue, coagulation, and desiccation of soft tissue in patients requiring surgery.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

for

Wavetronic 5000 Digital HF Surgical Unit

1. Submission Sponsor

LOKTAL MEDICAL ELECTRONICS IND. COM.LTDA- EPP
Rua Trona Constanzo, 156
São Paulo – SP - Brazil
CEP: 05516-020
Phone Number: 55 11 3722-0345
Fax Number: 55 11 3721-9438
Luciano Rodrigues Grillo, International Sales Manager

2. Submission Correspondent

Emergo
816 Congress Avenue, Suite 1400
Austin, TX 78701
Cell Phone: (720) 838.4113
Office Phone: (512) 327.9997
Fax: (512) 327.9998
Contact: Carrie, Senior Consultant, RA
Email: project.management@emergogroup.com

3. Date Prepared

October 6, 2015

4. Device Identification

Trade/Proprietary Name:	Wavetronic 5000 Digital HF Surgical Unit
Common/Usual Name:	Electrosurgical cutting and coagulation device and accessories
Classification Name:	Electrosurgical Cutting & Coagulation & Accessories
Classification Regulation:	878.4400
Product Code:	GEI
Device Class:	Class II
Classification Panel:	General and Plastic Surgery

5. Legally Marketed Predicate Device(s)

The Wavetronic 5000 Digital HF Surgical Unit is a state-of-the-art high-frequency energy device that is substantially equivalent to the current products that are already cleared for USA distribution under the following 510(k) Premarket Notification numbers:

- K082834Ellman International, Inc. Surgitron IEC
- K051956Sometech, Inc. Dr. OPPEL ST-501

6. Device Description

The Wavetronic 5000 Digital HF Surgical Unit is a non-sterile, reusable electrosurgical generator, which is designed to generate high frequencies (RF) of high voltage and low amperage current, operating at high frequency (4 MHz) to be employed by a variety of electrosurgical procedures. This action is achieved by front panel selection of waveforms and power levels. All selections are effected through push buttons and dials, and lamps, which give the operator feedback of status.

The Wavetronic 5000 Digital HF Surgical Unit is an electrosurgical cutting and coagulation device intended to remove tissue and control bleeding by use of high-frequency electrical current.

The device has four modes of operation;

1. Cut - a basic cutting mode that produces minimal heat.
2. Blend (cut and coagulation) – surface coagulation takes place simultaneously with cutting, with wave ratio being approximately 50/50.
3. Coagulation – a mode with high lateral heat emission.
4. Bipolar (bipolar coagulation mode) – bipolar coagulation mode is intended to remove tissue and control bleeding by use of high-frequency, electrosurgical current.

The control unit of the device front panel control provides the user with buttons, enabling to operate the device during therapy, and a display, which shows the set and indicated parameters. The therapeutic parameters can be set or adjusted any time through surgery, and displays the therapeutic method, the set power, and other necessary data required throughout the treatment.

The Wavetronic 5000 Digital HF Surgical Unit consists of the following main components:

- Wavetronic 5000 Digital high-frequency electromagnetic energy generator
- Optional wave selection (cut, blend, coag, bipolar)
- Footswitch
- Power cable

5. Indication for Use Statement

The Loktal Medical Electronics ind. E com. Ltda EPP - Wavetronic 5000 Digital HF Surgical Unit is intended for resection, ablation, excision of soft tissue, coagulation, and desiccation of soft tissue in patients requiring surgery.

6. Substantial Equivalence Discussion

The following table compares the Wavetronic 5000 Digital HF Surgical Unit to the predicate device with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5A – Comparison of Characteristics

Manufacturer	**Loktal Medical Electronics ind. E com. Ltda EPP**	**Ellman International, Inc.**	**Sometech, Inc.**
Trade Name	**Wavetronic 5000 Digital HF Surgical Unit**	**Surgitron IEC**	**Dr. OPPEL ST-501**
510(k) Number	K134036	K082834	K051956
			
Product Code	GEI	GEI	GEI
Regulation Number	21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400
Regulation Name	Electrosurgical Cutting and Coagulation Device and accessories	Electrosurgical Cutting and Coagulation Device and accessories	Electrosurgical Cutting and Coagulation Device and accessories
Indications for Use	The Loktal Medical Electronics ind. E com. Ltda EPP - Wavetronic 5000 Digital HF Surgical Unit is intended for resection, ablation, excision of soft tissue, coagulation, and desiccation of soft tissue in patients requiring surgery.	Non-ablative treatment of mild to moderate facial wrinkles and rhytides for skin phototypes I-IV The device is also indicated for: • Cutting, snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty IRAUP), myringotomy with effective hemorrhage control, epistaxis treatment, turbinate shrinkage, skin incisions, biopsy, cysts, abscesses, tumors, cosmetic repairs, development of skin flaps, skin tags, and blepharoplasty. • Blended Cutting and Coagulation: snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment, turbinate shrinkage, skin tags, papilloma keloids, keratosis, verrucae, basal cell carcinoma, nevi, fistulas, epithelioma, cosmetic repairs, cysts, abscesses, and	The Dr. OPPEL ST-501 is intended for the removal and destruction of skin legions and the coagulation of tissue. Non-sterile and reusable electrodes are used in conjunction with an electrosurgical handpiece and generator.

Manufacturer	Loktal Medical Electronics ind. E com. Ltda EPP	Ellman International, Inc.	Sometech, Inc.
Trade Name	**Wavetronic 5000 Digital HF Surgical Unit**	**Surgitron IEC**	**Dr. OPPEL ST-501**
		development of skin flaps. • Hemostasis: control of bleeding, epilation, telangiectasias. • Fulguration: basal cell carcinoma, papilloma, cyst destruction, tumors, verrucae, hemostasis. • Bipolar: pinpoint precise coagulation, pinpoint hemostasis in any field (wet or dry), snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment, and turbinate shrinkage.	
Prescription or OTC	Prescription	Prescription	Prescription
Device Technologies	Application of heat to the tissue w/ RF energy	Application of heat to the tissue w/ RF energy	Application of heat to the tissue w/ RF energy
Modes of Operation	Monopolar Blend Coagulation Bipolar	Monopolar Blend Coagulation Fulguration Bipolar	Monopolar Blend Coagulation Fulguration Bipolar
Electrical Protection	Type BF, Class I	Type BF, Class I	Type BF, Class I
Energy Type	Radiofrequency	Radiofrequency	Radiofrequency
Modes of Operation	Monopolar Bipolar	Monopolar mode used for indications for use: (Non-ablative treatment of mild to moderate facial wrinkles and rhytides for skin prototypes I-IV.). Bipolar mode used for other indications for use.	Monopolar Bipolar
Nominal Operating Power	60 to 100 Watts (Monopolar) 24 Watts (Bipolar)	120 Watts (Monopolar) 120 Watts (Bipolar)	125 Watts (Monopolar)
Output Peak Power	100 Watts	120 Watts	700 Watts
Power Supply	110/220Vac	110Vac	100/110/120/220/230/240 VAC
Output Frequency	4 MHz	4 MHz (monopolar) 1.7 MHz (bipolar)	4.0 MHz partially rectified
Interface	Buttons and knobs on the unit; there is a hand-piece	Buttons and knobs on the unit; there is a hand-piece	Buttons and knobs on the unit; there is a hand-piece

Manufacturer	Loktal Medical Electronics ind. E com. Ltda EPP	Ellman International, Inc.	Sometech, Inc.
Trade Name	**Wavetronic 5000 Digital HF Surgical Unit**	**Surgitron IEC**	**Dr. OPPEL ST-501**
	utilized to deliver the treatment.	utilized to deliver the treatment.	utilized to deliver the treatment.
Material of the Generator Case	Aluminum, Plastic, Stainless Steel	Plastic, Metal	Plastic, Metal
Unit Construction	Constructed of materials that conform to safety standards and requirement	Constructed of materials that conform to safety standards and requirement	Constructed of materials that conform to safety standards and requirement
Power Digital Display	Yes	No	No
Operating Temperature	5°C to 40°C	10°C to 40°C	10°C to 40°C
Operating Humidity	30% - 75%	30% - 75%	30% - 75%
Skin Temperature Monitoring	Based on Patient Feedback - Built-in IR thermometer	Based on Patient Feedback - Built-in IR thermometer	Based on Patient Feedback - Built-in IR thermometer
Power Level Adjustable via Applicator	NO	NO	NO
RF Energy Emission Indicator	YES	YES	YES
Applicator Dimensions	16 cm x 2 cm x 2.1 cm	0.8" × 0.8" × 6.3" (2 cm × 2 cm × 16 cm)	225(W) x 300(L) x 155(H)mm
Energy Source	110 – 220 VAC, max 3A, 50-60 Hz	100 – 240 VAC, max 4A, 50 – 60 Hz	100/110/120/220/230/240 VAC, 50/60Hz
System Dimensions	6.2” x 7.9” x 8.3” (16 cm x 20 cm x 21 cm)	9.5" × 7.1" × 16.5 " (24 cm × 18 cm × 42 cm)	225(W)x300(L)x155(H)mm
System Weight	9.3 lbs (4.2 kg)	26 lbs (11.8 kg)	22 lbs (10 kg)
Waveform	Sinusoid	Sinusoid	Sinusoid partially rectified
Treatment Duration	Treatment contingent – 5 sec to 5 minutes	3 – 5 min. per area	Not known
Dual Dispersive Patch Electrode Grounding	YES	YES	YES
Patch Electrode Contact Quality Monitoring	YES	YES	NO
RF Energy Emission Indicator	YES; Information displayed on the screen of the applicator and on the main screen of the unit.	YES	YES
External	115 V T 3, 15 AL, 250V	Available	Available

Manufacturer	Loktal Medical Electronics ind. E com. Ltda EPP	Ellman International, Inc.	Sometech, Inc.
Trade Name	**Wavetronic 5000 Digital HF Surgical Unit**	**Surgitron IEC**	**Dr. OPPEL ST-501**
Exchangeable Fuse	239 V T 1AL, 250V		
Blend Function	Yes	Yes	No
Coag Function	Yes	Yes	Yes
Bipolar Function	Yes	Yes	Yes
Portable	Yes	Yes	Yes
IEC Certification	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2	IEC 60601-1:2007 EN 60601-1:2007 EN 60601-2-2:2007 IEC EN 60601-2-2:2009	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2 ANSI / AAMI HF18
Optional Trolley Cart	Yes	Yes	Yes

7. Non-Clinical Performance Data

The device has been tested for applicable safety requirements. TheWavetronic 5000 Digital HF Surgical Unit complies with the applicable voluntary standards for biocompatibility. As part of demonstrating safety and effectiveness ofWavetronic 5000 Digital HF Surgical Unit and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, Loktal Medical Electronics Ind. e Com. Ltda completed a number of tests. The Wavetronic 5000 Digital HF Surgical Unit meets all the requirements for the overall design, biocompatibility, and electrical safety confirm that the output meets the design inputs and specifications. TheWavetronic 5000 Digital HF Surgical Unit passed all testing stated above as shown by the acceptable results obtained.

The following testing has been performed to support substantial equivalence:

8. Clinical Performance Data

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with a proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

9. Statement of Substantial Equivalence

It has been shown in this 510(k) submission that the differences, between the Wavetronic 5000 Digital HF Surgical Unit and the predicate devices listed above, do not raise any questions regarding its safety and effectiveness. Further, the Wavetronic 5000 Digital HF Surgical Unit utilizes the same type of technology as the predicate device. The Wavetronic 500 Digital HF Surgical Unit, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate devices.